IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ETHICON WAVE 1 CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

REPLY IN FURTHER SUPPORT OF MOTION OF DEFENDANTS TO EXCLUDE CERTAIN GENERAL OPINIONS OF BOBBY SHULL, M.D.

Introduction and Summary

As set forth in Defendants' initial brief and as set forth below, Dr. Bobby Shull departs from his expertise with respect to many of the opinions that he intends to offer in these cases. Plaintiffs' objections lack merit, and the Court should limit Dr. Shull's opinions consistent with Defendants' motion.

The Court should summarily reject Plaintiffs' argument that Defendants do not challenge Dr. Shull's Prosima opinions on the basis that Defendants' brief predominantly cites his Prolift report. With rare exceptions (which are referenced in Defendants' brief), Dr. Shull's Prosima report is identical to his Prolift report. Defendants' contentions about the fundamental flaws in Dr. Shull's methodology and his conclusions apply equally to each report, and therefore, citing to both would be redundant and unnecessary. In fact, Plaintiffs ignore that they have done the same thing in their challenges to Defendants' experts. *See, e.g.*, Doc. 2131, pp. 2, 15-17 (citing only Dr. Brian Flynn's TVT report).

I. The Court should preclude Dr. Shull from testifying that non-synthetic mesh procedures are a safer alternative for the surgical treatment of POP and/or that Prolift/Prosima present a heightened risk of complications as compared to those alternatives.

In those jurisdictions in which a plaintiff is required to prove the availability of a feasible, safer alternative design, the Court should preclude Dr. Shull from testifying about traditional surgical procedures, which are not a safer alternative design but an altogether different product. *See, e.g., Schmidt v. C.R. Bard, Inc.*, 2013 WL 3802804, at *2 (D. Nev. July 22, 2013) (finding that "non-mesh repair is not an alternative design and does not meet Plaintiff's burden to support" a design-defect claim); *Massa v. Genentech, Inc.*, 2012 U.S. Dist. LEXIS 36465, at *13-17 (S.D. Tex. Mar. 19, 2012) (citing *Brockert v. Wyeth Pharms., Inc.*, 287 S.W.3d 760, 770 (Tex. Ct. App. 2009)); *see also Caterpillar, Inc. v. Shears*, 911 S.W.2d 379, 385 (Tex. 1995) ("A motorcycle could be made safer by adding two additional wheels and a cab, but then it is no longer a motorcycle," and the law of product liability does not "impose liability in such a way as to eliminate whole categories of useful products from the market"). Plaintiffs have not explained why such testimony would be relevant in those jurisdictions.

II. The Court should not allow Dr. Shull to speculate about the duties of a medical device manufacturer.

A. Research/Testing

Plaintiffs ask without justification that the Court depart from its prior ruling in *Carlson v. Boston Scientific Corp.*, 2015 WL 1931311, at *15 (S.D. W. Va. Apr. 28, 2015), finding that Dr. Shull is not competent to critique Ethicon's testing. Plaintiffs suggest that Dr. Shull will merely opine about "whether or not the testing was in fact completed…." Doc. 2150, p. 10. As this Court has appropriately noted, "[w]hether Ethicon studied certain issues, provided information, or provided guidance are all examples of corporate conduct," which are beyond the purview of

expert testimony. Ex. H to Def's Motion, *Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473, Order at 18 (S.D. W. Va. Nov. 20, 2014). In any event, Dr. Shull would only be speculating about what any hypothetical testing would have revealed, which is entirely impermissible under the *Daubert-Joiner-Kumho* trilogy. Consistent with its prior rulings, the Court should disallow such testimony. *See, e.g., Carlson, supra; Trevino v. Boston Scientific Corp.*, 2016 WL 1718836, at *13 (S.D. W. Va. Apr. 28, 2016).

B. Adverse Event Reporting

Plaintiffs similarly argue that "Dr. Shull is not offering an opinion as the *nature* or *quality* of the adverse event reporting that should have occurred, but rather, he is stating that it did not occur." Doc. 2150, p. 11. Again, this is merely an assertion about corporate conduct, and there is nothing about Dr. Shull's experience as a clinician that affords him special knowledge to testify about what Ethicon did or did not do in this respect. *Bellew* at 18.

C. Regulatory Opinions

Plaintiffs wrongly claim that this Court in *Carlson, supra*, rejected a "nearly identical argument" that Dr. Shull could not offer regulatory opinions. Doc. 2150, p. 12 (citing *Carlson*, 2015 WL 1931311, at *16). In *Carlson*, the Court was considering Dr. Shull's warnings opinions, which are distinct from the regulatory opinions at issue here. Contrary to what Plaintiffs contend here, the Court in *Carlson* explicitly found that "Dr. Shull is unqualified to opine on regulatory requirements." *Id.*

D. Training

In support of their erroneous argument that Dr. Shull is qualified to testify about physician training, Plaintiffs inexplicably focus on Ethicon's IFUs and brochures rather than the training itself which is provided to physicians. At no point do Plaintiffs identify any background

of Dr. Shull that would demonstrate any competency in knowing the level of training that a medical device manufacturer is ostensibly required to provide about an FDA-cleared medical device. Opinions of this nature fall well within this Court's prior ruling that "[w]hether Ethicon studied certain issues, provided information, or provided guidance are all examples of corporate conduct" that are beyond the purview of expert testimony. *Bellew* at 18. In any event, Ethicon's provision of materials cleared by the FDA and other informational or promotional materials, including training materials send to licensed physicians are fully protected by the First Amendment, *see Sorrel v. IMS Health, Inc.*, 131 S. Ct. 2653, 2664 (2011) (collecting cases), and any such opinions by Dr. Shull should be excluded on this grounds as well.

E. Marketing

Although Dr. Shull claims that "Ethicon inappropriately marketed" the devices to "all physicians" (Ex. B to Def's Motion, Prolift Report at 3), Plaintiffs do not explain how a device manufacturer would be expected to adjudge the level of competence of surgeons using its products. In any event, the IFUs for these products limit their use to qualified surgeons.

Plaintiffs also make no attempt to address how Dr. Shull somehow has expertise that would enable him to testify that "Ethicon formed a special interest group with other mesh manufacturers to further market its prolapse kits" with the alleged purpose of financial gain. *Id.* at 13.

F. Legal Conclusions

The issue of whether Ethicon "exercise[d] due diligence" is a legal term of art that is clearly inappropriate for expert testimony. *See* Ex. B to Def's Motion, Prolift Report at 3. Further, this is an issue of corporate conduct that falls well beyond the purview of Dr. Shull's expertise as a urologist.

IV. The Court should preclude Dr. Shull from testifying about product design, alleged mesh deformation, and other biomaterials opinions.

A. Dr. Shull is not qualified.

Plaintiffs have not shown what is different about Dr. Shull's experiences that would suddenly make him a product design expert. Defendants do not argue that Dr. Shull should be prohibited from discussing his clinical observations of mesh deformation. What he should not be allowed to do, however, is to testify that his clinical observations are related to degradation or that a device designed in a different way would have mitigated those risks, particularly given the lack of peer-reviewed medical literature finding that any evidence of degradation is of clinical significance. Dr. Shull lacks the credentials necessary to form such biomaterials opinions. *See Winebarger v. Boston Scientific Corp.*, 2015 U.S. Dist. LEXIS 53892, at *103-04 (S.D. W. Va. Apr. 24, 2015) (finding that urogynecologist could not testify as to mesh design).

B. Smaller Pore, Heavier Weight Mesh

Once again, Dr. Shull is not qualified to offer an opinion about this subject. Furthermore, Plaintiffs overlook that Dr. Shull cannot -- and does not -- identify the polypropylene volume at which efficacy can be obtained and adverse events avoided. He offers nothing other than the hypothesis that some form of mesh may exist in which the volume of polypropylene is low enough to avoid adverse events but high enough to be sufficiently effective. What that volume is, he does not know. And whether this hypothetical alternative exists, he does not know. In this context, his opinions are entirely speculative, and they should be excluded. *See, e.g., Conklin v. Novartis Pharmas. Corp*, 2012 WL 4127295 (E.D. Tex. 2012).

VI. The Court should exclude Dr. Shull's warning opinions.

For the reasons articulated by Defendants and previously determined by the Court, [insert case citation], the Court should preclude Dr. Shull from providing warning opinions. Should the

Court find that Dr. Shull is competent to provide limited warnings opinions, the Court should also find that Defendants' clinician experts with similar qualifications are competent to also provide warning opinions.

CONCLUSION

For the foregoing reasons and those set forth in Defendants' initial brief, the Court should limit Dr. Shull's testimony in this case.

Respectfully submitted,

/s/William M. Gage
William M. Gage
Butler Snow LLP
1020 Highland Colony Parkway
Suite 1400 (39157)
P.O. Box 6010
Ridgeland, MS 39158-6010
(601) 985-4561
william.gage@butlersnow.com

/s/ David B. Thomas
David B. Thomas (W. Va. Bar #3731)
Thomas Combs & Spann PLLC
300 Summers Street
Suite 1380 (25301)
P.O. Box 3824
Charleston, WV 25338
(304) 414-1807
dthomas@tcspllc.com

COUNSEL FOR DEFENDANTS
ETHICON, INC. AND
JOHNSON & JOHNSON

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ETHICON WAVE 1 CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

CERTIFICATE OF SERVICE

I, William M. Gage, certify that on May 16, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ William M. Gage

William M. Gage
Butler Snow LLP
1020 Highland Colony Parkway
Suite 1400 (39157)
P.O. Box 6010
Ridgeland, MS 39158-6010
(601) 985-4561
william.gage@butlersnow.com

ButlerSnow 31184269v1